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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,134	06/09/2005	Hanbiao Yang	PU4976USw	6917
23347	7590	07/10/2006	EXAMINER CHU, YONG LIANG	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			ART UNIT 1626	PAPER NUMBER

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/538,134	YANG ET AL.
	Examiner Yong Chu	Art Unit 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 June 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-36 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) 6,13,14,23,29-35 and 45-47 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5,7-12,15-22,24-28,36 and 42-44 is/are rejected.
- 7) Claim(s) 36 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/21/2005</u> <u>6/19/2005</u>	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

Claims 37-40, and 41 are cancelled by amendment filed on 9 June 2005. Claims 7, 26, 31, 33, 35-36, 42, 45, and 47 are amended by amendment filed on 9 June 2005. Therefore, claims 1-36, and 42-47 are currently pending in the instant application.

### ***Information Disclosure Statement***

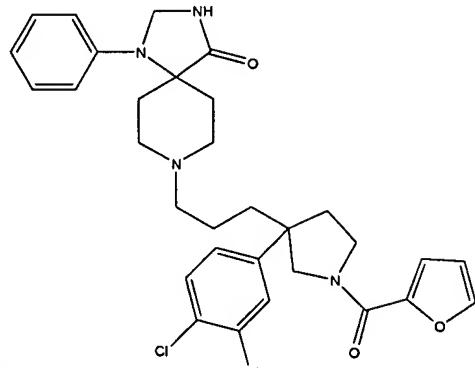
Applicant's Information Disclosure Statements, filed on 21 April 2006 have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

### ***Priority***

This application is a 371 of PCT/US03/39618, filed on 12 December 2003. Applicants claim the benefit of for U.S. Provisional Patent Application 60/433,372 filed on 13 December 2003 and 2002, under 35 U.S.C. §119(e).

### ***Response to Restriction***

The response to the restriction request with election with *traverse* of Group I (e.g. claims 1-30, 36, and 42-47) and species of the compound disclosed in the Specification



as Example 2

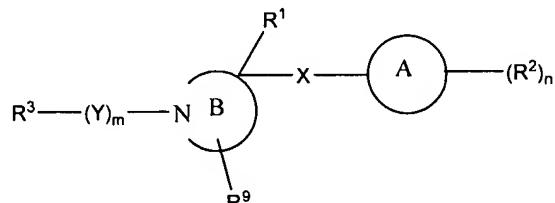
by Applicants' representative, Bonnie L.

Deppenbrock dated on 8 June 2006, has been considered.

Applicants' election with traverse is treated as without traverse since Applicants did not provide base for the traverse.

### ***Status of the Claims***

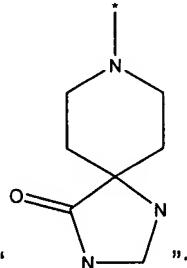
The scope of the invention of the elected subject matter is as follows:



Compounds of formula (I),

, depicted in

claim 1, wherein:



Ring A with two geminal R<sup>2</sup>'s is ";

Ring B is a saturated 4 or 5-membered ring containing the depicted ring nitrogen;

R<sup>1</sup> is optimally substituted phenyl;

R<sup>9</sup> is H;

Y is -C(O)-, or -C(O)O-;

The remaining substituents are defined as in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, claims 6, 13-14, 23, 29-35, 45-47, and the remaining subject matter of claims 1-5, 7-12, 15-22, 24-28, 36, and 42-44 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Therefore, Claims ~~1-5, 7-12, 15-22, 24-28, 36, and 42-44~~ are ready to examine.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Objections***

Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 36 is a duplicate of claim 1. The intend to use the compounds for use in medical therapy as depicted in claim 36 does not further limit the scope of the claimed compounds in claim 1.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is stated that R<sup>1</sup> is optionally substituted aryl. However, there is lack of definition of the group "substituted" by.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is stated that A ring is optionally N-substituted. However, "N-substituted" is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 24-28, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the compounds disclosed in claim 2, and 3, does not reasonably provide enablement for making the compounds in claims 1, 4-6, 24-30, and 36. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. For example, claim 1 depicts a compound with general formula (I) with various variables  $R^0-R^9$ , X, Y, ring A, and ring B, wherein Ring A is monocyclic and bicyclic ring with numerous substituents, as well as ring B. However, the Specification does not teach the reaction conditions and the starting materials used for making the claimed compounds except in Examples on page 52-79 with well defined chemical structures claimed in claims 2-3.

#### ***Claim Rejections - 35 USC § 102(b)***

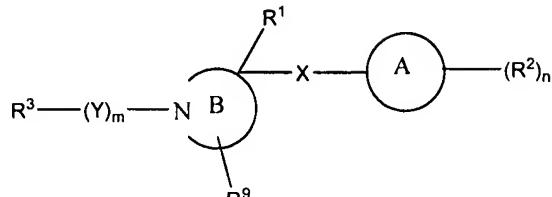
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

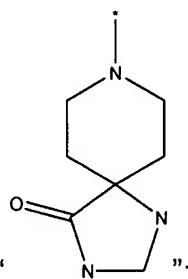
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7-12, 17, 26-28, 36, 42-44 are rejected under 35 U.S.C. 102 (b) as being anticipated by Burkholder et al., WO 9426735 (*publication date 11/24/1994*).

Applicants instant elected invention in claims 1, 4, 5, 7-12, 17, 26-28, 36, and 42-



44 teaches compound of formula , depicted in  
claim 1, and their a pharmaceutically acceptable salts thereof wherein:



Ring A with two geminal  $R^2$ 's is " ;

Ring B is a saturated 4 or 5-membered ring containing the depicted ring nitrogen;

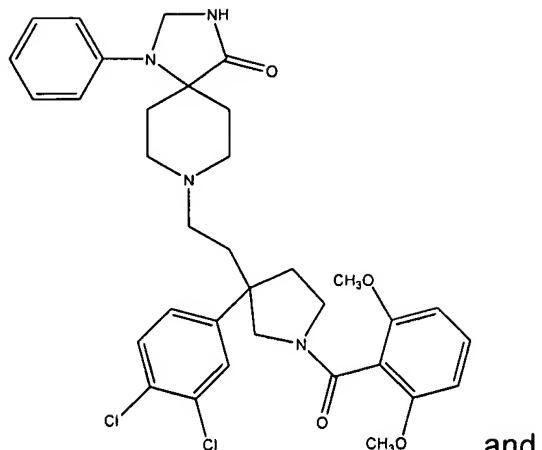
$R^1$  is optimally substituted phenyl;

$R^9$  is H;

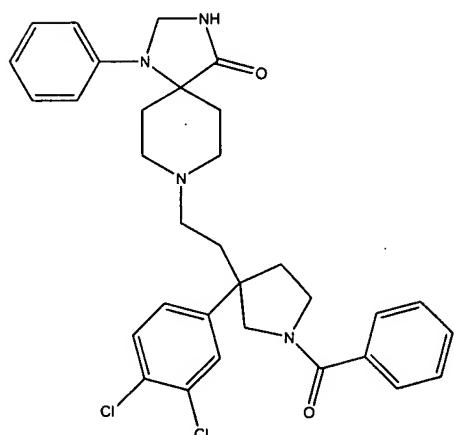
$Y$  is  $-C(O)-$ , or  $-C(O)O-$ ;

The remaining substituents are defined as in claim 1.

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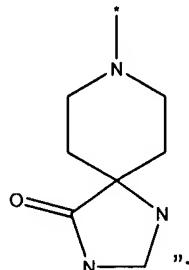


Burkholder et al. teach specific compounds



(see attached STN search result), read on the instant

claims 1, 4, 5, 7-12, 17, 26-28, 36, and 42-44, wherein:

Ring A with two geminal R<sup>2</sup>'s is ";

Ring B is a saturated 4 or 5-membered ring containing the depicted ring nitrogen;

R<sup>1</sup> is phenyl di-substituted with Cl;R<sup>2</sup> : two geminal R<sup>2</sup>'s are taken together to form a spiro, saturated 5-6-membered ring

having 0-3 heteroatoms selected from O, P, S, or N, said fused or spiro ring being

optionally substituted by one or more  $R^8$ , wherein  $R^8$  is  $R^7$ , wherein  $R^7$  is  $R^0$ , wherein  $R^0$  is aryl;

$R^3$  is optimally substituted aryl;

$R^9$  is H;

Y is  $-C(O)-$ ;

X is C1-5 alkylene chain;

m is 1;

n is 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

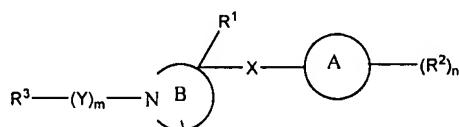
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-12, 15-22, 24-28, 36, and 42-44 are rejected under 35 U.S.C. 103

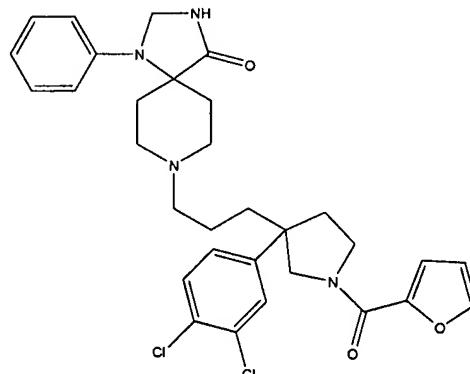
(a) as unpatentable over Burkholder et al., WO 9426735 (*publication date 11/24/1994*), in view of Wikipedia on heterocyclic compound online version where furan and pyridine are exemplified as closely related heterocyclic compounds.

Applicants instant elected invention in claims 1-5, 7-12, 15-22, 24-28, 36, and 42-



44 teach compounds of formula (I),

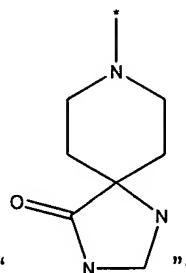
, depicted in claim 1



with a elected species of compound

, and their

pharmaceutical composition, thereof wherein:



Ring A with two geminal R^2's is “ ”;

Ring B is a saturated 4 or 5-membered ring containing the depicted ring nitrogen;

R^1 is optimally substituted phenyl;

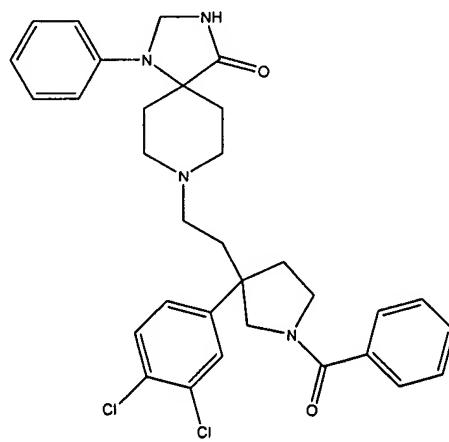
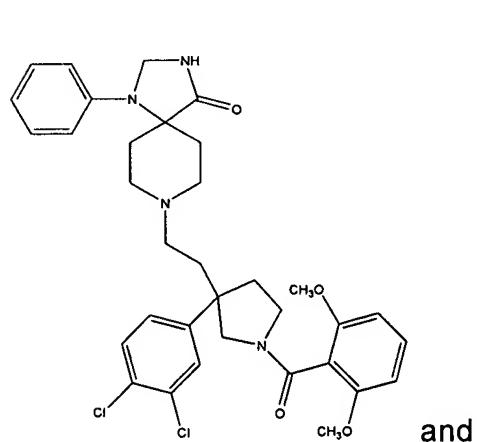
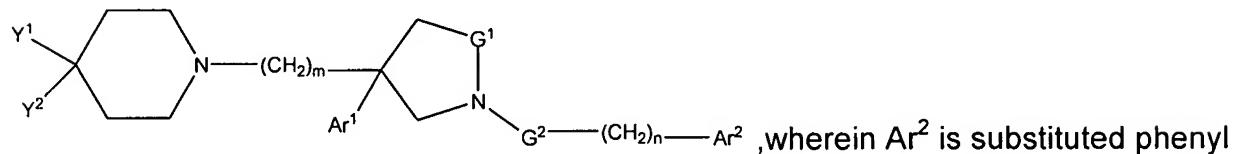
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 $R^9$  is H; $Y$  is  $-C(O)-$ , or  $-C(O)O-$ ;

The remaining substituents are defined as in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)

Burkholder et al. teach a class of compounds of general chemical formula

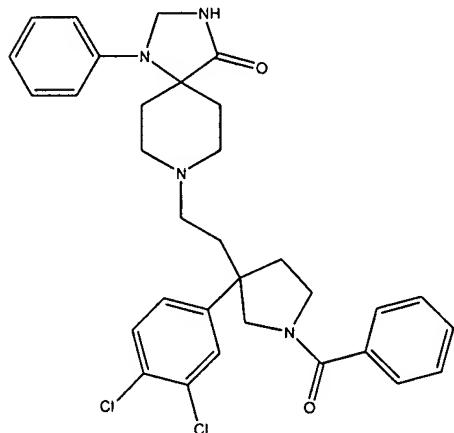


. Burkholder et al.

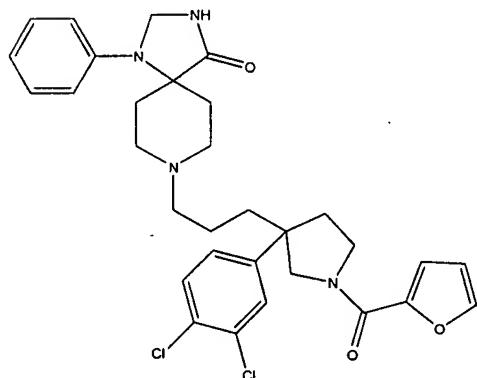
teach a group of similar compounds of Examples, depicted in the Specification. The anticipating species was delineated *supra*.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The differences between the prior art of Burkholder et al.



and the instantly elected species



, are that “R<sup>3</sup>” of the Burkholder compound is phenyl

group, not furan as in the said claimed compound. The difference of “X”, wherein “ethyl” group in Burkholder compound over “propyl” group in the said claimed compound is considered non-significant in view of “X” is defined as C1-5 alkylene in the instant application. However, Burkholder compounds also include ones with Ar2 substituents as heterocycl-. Wikipedia online version exemplifies furan and pyridine as closely related heterocyclic compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious over the compound taught by Burkholder because it is well established that the substitution of furan with heterocyclic group on a known compound is not a patentable modification absent unexpected or unobvious results, especially the chemistry for such modification are well-known, and the starting material for making such modification are commercial available from Aldrich. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lahr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). Since the elected species are unpatentable, all the claimed compounds are become unpatentable due to the obviousness among the elected species and the rest claimed compounds. However, the method to use of the product type application could be the alternative.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

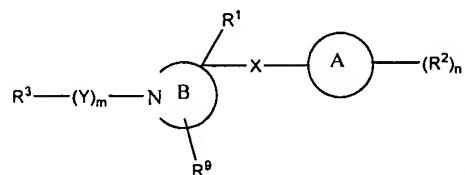
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-12, 15-22, 24-28, 36, and 42-44 of this application conflict with claims 1-25, 31, and 37-39 of U.S. Pat. App. Num. 2006/0052595 (10/538,145). 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-5, 7-12, 15-22, 24-28, 36, and 42-44 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-25, 31, and 37-39 of copending U.S. Pat. App. Num. 2006/0052595. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: compounds



and their pharmaceutical compositions.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

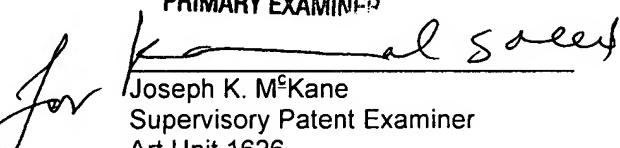
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>c</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
Yong Chu, Ph.D.  
Patent Examiner  
Art Unit 1626

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER

  
\_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626